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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,787	12/13/2000	Grethe Rasmussen	3469.234-US	6609

25908 7590 01/28/2003

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/28/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,787

Applicant(s)

RASMUSSEN ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Prosecution Re-opened

In view of the request for interference with US Patent NOs. 6,107,265 and 6,162,782, filed by the applicant based on the foreign priority date 5-9-1990, the prosecution has been reopened after the perusal of the priority document 1159/90. In this regard applicant's attention is drawn to the to the grant of the priority statement by the Examiner.

Claims 32-54 are currently pending and present for examination in this application.

Priority

Receipt is acknowledged of papers filed on 12-13-2000 purporting to comply with the requirements of 35 U.S.C. 119(a)-(d) and they have been placed of record in the file. However, Examiner has not granted the priority date of 5-9-90, based on the priority document 1159/90, because, while the claims in the instant application are very broad claiming compositions comprising or consisting essentially of or consisting of any or all fungal endoglucanase/cellulase free of cellobiohydrolase components and active in a broad pH range of 3-10, the claims in the above foreign patent, based on which the priority date is claimed, are limited to detergent compositions comprising specifically an endoglucanase/cellulase isolated from *H.insolens* DSM 1800. Furthermore the foreign patent is silent regarding the pH range of the composition. The priority document does not support the full scope of the instant claims and therefore the priority date 5-9-90 is not granted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 39, 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 33, 39, 45 recite the phrase "composition as defined in claim 32, having a pH ranging from 3 to 10. It is not clear to the Examiner as to what applicants mean by the above phrase. It is not clear whether applicants intend to make different compositions with varied pH, i.e., ranging from 3 to 10 and if so at what pH intervals, or whether applicants are claiming a composition whose enzyme will be active in the pH range of 3 to 10.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a detergent effective amount of one or more surfactants and 0.0001 to 2.5 percent by weight of said composition a cellulase/endoglucanase enzyme isolated from *H.insolens* and having an amino acid sequence SEQ ID NO:2, or an identical enzyme isolated from *F.oxysporum* and having an amino acid sequence SEQ ID NO:4 does not reasonably provide enablement for such a composition comprising or consisting of any cellulase/endoglucanase, including mutants, variants and recombinants isolated from any fungi.

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The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 32-54 are so broad as to encompass any fungal endoglucanase/cellulase. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of fungal endoglucanases/cellulases broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequences of only two enzymes.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any

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protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any fungal endoglucanase/cellulase because the specification does not establish: (A) a rational and predictable scheme for modifying any fungal endoglucanase/cellulase amino acid residues with an expectation of obtaining the desired and specific biological functions; (B) regions of the above protein (enzyme) structure which may be modified without effecting its desired characteristics/activity; (C) the general tolerance of fungal endoglucanases/cellulases to modification and extent of such tolerance; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any or all fungal endoglucanases/cellulases with an enormous number of amino acid modifications of the enzymes with SEQ ID NOS: 2 and 4. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of fungal endoglucanases having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

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Claims 32-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 32-54 are directed to compositions comprising or consisting fungal endoglucanases/cellulases, including variants, mutants and recombinants. Claims 32-54 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue and fragments that have not been disclosed in the specification. No description has been provided of all the polypeptides including the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of two polypeptides with SEQ ID NO:2 and 4 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences derived from SEQ ID NO:2 or 4 or all the polypeptides encompassed by claims 32-54, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of functions and with the potentiality of generating many different antibodies. Therefore many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species

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within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarkson (a) et al. (US 6,107,265, 8-22-2000) or Clarkson(b) et al. (US 6,162,782, 12-19-2000). Claims 32-54 in this instant application are drawn to a composition comprising of a detergent effective amount of one or more surfactants and a fungal cellulase preparation wherein the fungal cellulase preparation comprises or consisting essentially of or consisting of an endoglucanase which is free from CBH activity and wherein such an enzyme is homogenous and produced from a genetically modified organism, a fungus and the endoglucanase has CMC-endoase activity of at least 50 CMC-endoase units/mg of total cellulase.

Clarkson (a) et al. and Clarkson(b) et al. also teach compositions comprising a cleaning effective amount of a surfactant or a mixture of surfactants and a fungal cellulase composition wherein the fungal cellulase is free from CBH activity, produced from a genetically modified

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organism such as a fungus and wherein the fungal cellulase composition is homogenous comprising no other protein component. Both the above references disclose similar inventions if not identical inventions.

Using the above two references, it would have been obvious to one of ordinary skill in the art to change the specific amounts of surfactants and the amounts of the enzyme in the composition and arrive at the above invention claimed in claims 32-54. One of ordinary skill in the art would have been motivated to do so as cleaning compositions and detergent compositions have immense commercial applications. One of ordinary skill in the art would have a reasonable expectation of success since the references teach compositions similar, if not identical, to that claimed in the instant claims and their use.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

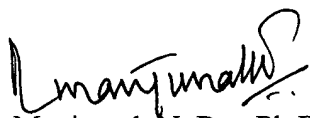
Applicants may argue that the references do not teach the limitations of pH and the endoase activity. However, since the references teach compositions comprising fungal cellulase/endoglucanases, examiner takes the position that such characteristics are inherent to the enzyme in the reference. Furthermore, Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

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Examiner has used the above references since the priority date for the instant application has not been granted by the Examiner (see under priority above).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Manjunath N. Rao Ph.D.

1/27/03

MANJUNATH RAO
PATENT EXAMINER